

## 1.0 PROJECT OVERVIEW & RELEVANCE

This project will address the **Research Question**: Can a non-intrusive physical activity tracking tool, combined with a group education session and advice from a physiotherapist (PT), increase physical activity in patients with knee osteoarthritis (OA)? We focus on knee OA because it is common (affecting 1 in 10) and can be debilitating.<sup>1,2</sup> Being physically active improves pain, mobility and quality of life;<sup>3-5</sup> however, less than half of patients are active.<sup>6</sup> Combining the best evidence in OA care and digital technology, we propose a new model of care for improving physical activity in patients with OA. Our **primary objective** is to determine whether a model involving 1) the use of Fitbit® Flex™, a commercially available physical activity tracker ([Figure 1](#)), 2) a group education session, and 3) remote coaching by a PT can improve physical activity and reduce sedentary time in patients with knee OA. This model of care is in line with the goal of Mary Pack Arthritis Program (MPAP) to optimize activity independence of OA patients with MPAP's available human resources. In the proposed proof-of-concept randomized controlled trial (RCT), we **hypothesize** that compared to a control group, participants in the Intervention Group will 1) increase moderate/vigorous physical activity (MVPA), 2) reduce sedentary time, 3) improve in OA disease status, and 4) improve in their self-efficacy of OA management.

In light of the evidence that regular physical activity promotes certain cognitive functions—especially, memory<sup>1</sup> and executive functions<sup>2,3</sup>—our **secondary object** is to examine whether individuals in the Intervention Group will show improved cognitive function over the intervention period compared to the control group. We hypothesize that individuals in the Intervention group will show improvements in cognition—especially in executive functions—compared to the control group and we will explore whether these effects are strongest for those with the greatest uptake of MVPA.

A **tertiary object** is to examine the pre-intervention factors that predict the degree to which individuals in the Intervention group increase MVPA and reduce sedentary time. There is burgeoning evidence that the brain's response to health promotion messages predicts subsequent positive behaviour change,<sup>4</sup> including the reduction of sedentary time among sedentary adults.<sup>5</sup> Thus, we will be using functional magnetic resonance imaging (fMRI) to examine the brain's response to promotional messages to increase MVPA and decrease sedentary time among individuals randomized to the Intervention Group. Based on previous research,<sup>5</sup> we will examine a specific region of interest—the ventromedial prefrontal cortex—and see if functional activation in this region predicts increases in MVPA and decreases in sedentary time over the study period.

## 2.0 BACKGROUND: Physical Activity in Osteoarthritis: Solid Evidence, Weak Uptake

Arthritis is the most common cause of severe chronic pain and disability worldwide.<sup>7,8</sup> There is evidence that physical activity can improve pain, mobility and quality of life in people with OA.<sup>3-5</sup> Guidelines by the OA Research Society International recommend the use of exercise for knee OA.<sup>9</sup> The Canadian Physical Activity Guidelines also recommend at least 150 minutes of moderate-intensity activity per week for maintaining good health, including for people with OA.<sup>10</sup> Physical activity is an essential first-line treatment<sup>9</sup> partly due to its effect in managing weight.<sup>11,12</sup> Furthermore, it reduces risks of metabolic syndromes, such as the level of plasma glucose.<sup>13</sup> The gap between this knowledge and the 'action' of being physically active, however, is astounding. The 2011 Canadian Community Health Survey reported that over 57% of people with arthritis were physically inactive during their leisure time, compared to 46% of those without arthritis.<sup>14</sup> This concurs with a 2013 systematic review that only 13% of people with OA

met the physical activity guidelines.<sup>15</sup> A 2011 study using accelerometers as an objective measure found over 90% of people with knee OA did not meet the physical activity guidelines.<sup>16</sup> The current public health message is that *being active is good*, but OA patients may be reluctant to be active due to pain.<sup>17-19</sup> For these people, maintaining some level of activity is still important. Recent studies indicate that sedentary lifestyle\* (i.e., too much sitting) is a predictor of poor health outcomes.<sup>20-24</sup> Interestingly, light activities\*, even done below the moderate intensity level (e.g., daily tasks done while standing or walking slowly), provide health benefits.<sup>13;25;26</sup> The detrimental health effect of 'sitting too much' is independent of the person's activity level. Hence, there is a need for interventions to improve MVPA and decrease sedentary behaviours.

## 2.1 Evidence on Interventions for Improving Physical Activity

Several modifiable risk factors are associated with low physical activity participation in people with arthritis. These include lack of motivation,<sup>17</sup> doubts about the effectiveness of exercise,<sup>19</sup> and lack of health professional advice.<sup>27</sup> Once patients start being active, they need feedback on their progress. A 2010 Cochrane review concluded that 'graded exercise activity', which initially focuses on simple exercises for weaker muscles and less painful areas before gradually increasing to more challenging activities, is effective for improving adherence to physical activity programs in chronic musculoskeletal conditions.<sup>28</sup> Refresher sessions are recommended to improve performance accuracy.<sup>29</sup> Progression of activities can be guided by a PT.<sup>28</sup> Online consultation for arthritis patients has been recently studied in a RCT.<sup>30</sup> Participants had access to an arthritis exercise website. The Intervention Group also received distant supervision by a PT via emails. The study shows a significantly greater improvement in moderate-level activity in the Intervention Group at six months (38% vs. 22% in the Control Group) and nine months (35% versus 11%).<sup>30</sup> It did not, however, assess the effect on sedentary time reduction. Given the low activity participation, multi-faceted interventions that enable patients to obtain feedback from health professionals and receive motivational support have potential to address the gap in care.

## 2.2 Evidence on Interventions for Improving Cognition

Engaging in regular physical activity can have the additional benefit of improving cognitive functioning.<sup>6</sup> Although several previous RCTs of 6 months or longer have found that exercise training programs—both resistance and aerobic—improves cognition among adults who were initially sedentary, the degree to which a shorter, technology-based intervention promotes cognition is unknown. In light of the fact that a sedentary lifestyle in midlife is a risk factor for excessive cognitive decline with advanced age<sup>7</sup> and the aforementioned evidence that people with OA tend to be sedentary, addressing this question in this population is highly relevant.

## 3.0 PROGRESS TO DATE

In a pilot study, **Feehan** and **Li** recruited 22 healthy individuals to assess the accuracy of two accelerometers measuring activity (Actigraph<sup>TM</sup> GT3X: the most commonly used accelerometer for objective physical activity measure,<sup>31;32</sup> and SenseWear<sup>TM</sup> Mini: a newer multi-sensor activity monitor that has recently been used for research purposes). Although both accelerometers were able to accurately record MVPA, SenseWear performed notably better than Actigraph in differentiating between sedentary and light activities (SenseWear sensitivity = 0.98; specificity = 0.70; positive predictive value = 0.81).<sup>33</sup> Based on these findings, we will use SenseWear as the primary outcome measure. To assess whether it is feasible for people with

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\* **Sedentary behaviour** = Any waking behaviour with an energy expenditure of < 1.6 metabolic equivalent tasks (METs) or less while in a sitting or reclining posture. **Light activity** = Activities with an energy expenditure of 1.6-2.9 METS.

joint pain to use physical activity trackers for an extended period of time, we recruited 10 patients with rheumatoid arthritis (RA) to wear a Fitbit Flex for four weeks and a SenseWear Mini in Weeks 1 and 4. All participants complied with the protocol. The ease of use of Fitbit and Sensewear was rated 4.8 and 3.4 (on a 5-point scale), respectively, indicating the feasibility for people with joint pain to wear these devices for an extended period.<sup>34</sup>

#### 4.0 METHODS (Table 1: Timeline)

The proposed project is guided by the Action Cycle of Graham's *Knowledge-to-Action Process*.<sup>35</sup> We will use a **mixed-methods approach**, involving a proof-of-concept RCT and in-depth interviews. The proof-of-concept study will employ a stepped wedge RCT design, whereby the intervention will be sequentially rolled out to participants over a number of time periods.<sup>36,37</sup> The order in which individuals receive the intervention will be determined at random. The strength of this design is that it can properly address the efficacy question, while avoiding the dilemma of withholding the intervention to some participants, as in a parallel group design. Patients are eligible if they 1) have a physician confirmed diagnosis of knee OA, or are 50 years or older and have felt pain/discomfort in or around the knee during the previous year that lasted more than 28 separate or consecutive days, 2) have no previous diagnosis of RA, psoriatic arthritis, ankylosing spondylitis, polymyalgia rheumatica, connective tissue diseases, fibromyalgia or gout, 3) have no history of using disease-modifying anti-rheumatic drugs or gout medications, 4) have no prior knee arthroplasty and not on the waiting list for total knee replacement surgery, 5) have not had surgery in the back, hip, knee, foot, or ankle joints in the past 12 months, 6) have no history of acute injury to the knee in the past 6 months, and 7) have an email address and daily access to a computer with internet connection. We will exclude people who 1) have a body mass index of greater than or equal to 40, 2) have received a steroid injection in a knee in the last 6 months, 3) have received a hyaluronate injection in a knee in the last 6 months, 4) use medication that may impair activity tolerance (e.g., beta blockers), and 5) face a level of risk by exercising as identified by the Physical Activity Readiness Questionnaire (PAR-Q).<sup>38</sup> In the ancillary neuroimaging study, interested participants will be further screened for eligibility before randomization by a trained and experienced MRI technician.

Study Procedure (Figure 2): Participants will be recruited from the wait list of the MPAP. In 2012-13, 250 OA patients had been referred to MPAP, approximately 50% met our eligibility criteria. The wait time for a PT appointment for OA is 6 months. Participants will also be recruited from community health centres within metropolitan areas of Delta, Surrey, Burnaby, New Westminster, Langley, Coquitlam, Maple Ridge, Chilliwack, Mission, and Abbotsford, social networking websites (Craigslist, Twitter, Kajiji, Facebook), the Arthritis Research Canada website, Arthritis Consumer Expert (ACE)'s JointHealth e-blast, consumer collaborators' groups newsletters, websites and social media (e.g. CARP, the Arthritis Society), and VCHRI weekly e-update which is distributed to staff, researchers, faculty, and affiliates of VCHRI. Eligible participants will complete the baseline measures, which includes wearing an activity monitor for 1 week, completing an online questionnaire, and attending a cognitive assessment session at Vancouver General Hospital. Following completion of the baseline measures, participants will be randomly assigned to the Intervention Group (known as the Immediate Intervention Group) or Waiting List Control Group (known as the Delayed Intervention Group) in 1:1 allocation ratio. Randomization will be performed using computer-generated random numbers in variable block sizes, which are necessary to ensure adequate allocation concealment.

The Immediate Intervention Group will begin the intervention right after randomization. Participants will be invited to attend a group session with 3-4 other participants. They will receive instructions to set up their Fitbit and 40 minutes of standardized education provided by a MPAP PT on physical activity. At the end of the session, the PT will help participants set activity goals and provide personalized activity options. In Months 1 and 2, participants will use the Fitbit Flex. Information about their physical activity will be captured by the Fitbit and wirelessly synchronized with the manufacturer's online app. The app will display personalized activity summaries, and can be downloaded and shared with the PT. The PT will review the progress with participants via 20-minute biweekly phone calls and progressively modify their activities. Participants may also contact the PT via email if they have questions. In Months 3-6, participants will continue wearing the Fitbit and have access to a PT via email as needed, but no biweekly phone calls. The Delayed Intervention Group (Control Group) will receive the full intervention two months later. Both groups will receive a monthly study newsletter during the 6-month study period.

Follow-up assessments will be performed at the end of Month 2, 4 and 6. To better understand the reasons people do or do not maintain recommended levels of physical activity, participants will be interviewed for one hour by phone after the intervention. Interviews will focus on 1) barriers/facilitators to being physically active, 2) their experience with the intervention, and 3) the nature of activities they engage in.

**Outcome Measures:** Our **primary outcome measure** will be time spent in MVPA. In addition, we will record the time spent in sedentary behaviours. Tierney<sup>39</sup> showed that SenseWear was a valid tool for estimating energy expenditure during daily activities in people with arthritis (ICC = 0.72). It can be worn on the upper arm 24 hours a day; hence, it can capture a full picture of physical activity and sleep patterns.<sup>40;41</sup> An important feature of SenseWear is its ability to differentiate between sedentary and light activities,<sup>33</sup> making it an ideal instrument to assess both active and sedentary behaviours. We will calculate the average daily MVPA accumulated in bouts per day. A bout is defined as  $\geq 10$  consecutive minutes at the level of  $\geq 3$  METs (i.e., the lower bound of MVPA), with allowance for interruption of up to 2 minutes below the threshold.<sup>42</sup> For sedentary behaviours, we will calculate the average daily time spent with an energy expenditure of  $< 1.6$  METs, occurring in bouts of  $\geq 20$  minutes during waking hours.<sup>24;26;43;44</sup>

**Secondary outcomes** will be measured with 1) the Community Health Activities Model Program for Seniors (CHAMPS) 2) the Knee Injury & OA Outcome Score (KOOS),<sup>45;46</sup> and 3) the Partners in Health Scale.<sup>47</sup> The CHAMPS survey provides valid and reliable estimates of physical activity in older adults and is shown to be sensitive to change in physical activity intervention studies<sup>8-11</sup>. The questionnaire asks participants about their current engagement in 40 different activities including household chores, recreational chores, and leisure and social activities. The KOOS consists of five subscales: knee pain, stiffness, daily activity, sports/recreation, and quality of life. It was originally developed for people recovering from anterior cruciate ligament and meniscus injury and has been validated in people with OA.<sup>45;46</sup> The Partners in Health Scale is a 12-item measure designed to assess self-efficacy, knowledge of health conditions and treatment, and self-management behaviours such as adopting a healthy lifestyle (Cronbach's  $\alpha=0.82$ ).<sup>47</sup> In addition, motivation for physical activity will be measured with Rhodes's 7-point Likert-type Theory of Planned Behaviour questionnaire.<sup>48-50</sup> It consists of

16 items measuring all components of the theory. We will also track the adverse events (falls, cardiovascular and musculoskeletal events)<sup>51</sup> at the follow-up assessments.

**Tertiary outcomes** will be changes in cognitive functioning, led by Dr. Teresa Liu Ambrose. Participants will attend the 1-hour cognitive assessment session at Vancouver General Hospital and complete the following computer-based assessments: 1) the Kirby task<sup>12</sup>; 2) the Stroop task<sup>13</sup>; 3) list-sorting task; and 4) picture sequence memory test. Each task requires approximately 10 minutes. The Kirby task is a delay discounting task and consists of 27 trials in which participants are asked to state their preference for a smaller, immediate monetary reward or a larger, delayed monetary reward. The Stroop task is a measure of response inhibition consists of 126 trials, equally distributed among neutral, congruent, and incongruent trial types, in which participants are asked to identify the color of the font for different words (both color and non-color words). The final two tasks are contained in the NIH Cognition Toolbox.<sup>14</sup> The list sorting task assesses working memory by asking participants to repeat the names of orally- and visually-presented stimuli in order of size, from smallest to largest. The number of items per set increases from one trial to the next and is discontinued once 2 trials of the same length are failed. The picture sequence memory test assesses episodic memory by having participants remember a sequence of actions embedded within a story based. Specifically, participants rearrange several pictures on the computer screen to match the sequence of events in the story. Three trials are completed. In addition, participants will complete a pencil-and-paper task, consisting of the Montreal Cognitive Assessment (MoCA).

Neuroimaging Procedure: Interested participants may also partake in a 1-hour neuroimaging session at the UBC 3T Magnetic Resonance Imaging Centre. They are eligible for MRI scanning if they 1) do not have cardiac pacemaker, wires, or defibrillator, 2) do not have a metal in eye or orbit, 3) do not have a ferromagnetic aneurysm clip, 4) do not have claustrophobia, and 5) are not pregnant. This session will be scheduled to occur prior to randomization. Scanning time will be approximately one hour. For the first 30 minutes, participants will be asked to lie at rest in the scanner while structural scans are obtained. The second 30 minutes will involve fMRI, during which participants will view a series of health promotion messages (both to increase MVPA and to reduce sedentary behaviour; n = 50 messages). After each message, participants will be asked to reflect upon those messages, including how they would apply those messages to their own lives. The fMRI procedure is based on a recent study of sedentary adults.<sup>5</sup> The inclusion of a baseline neuroimaging procedure will allow us to address two important aims. First, we will use fMRI to examine the brain's response to promotional messages to increase MVPA and decrease sedentary time, as well as how the brain responds differently when prompted to think about the long-term consequences of consuming unhealthy, yet palatable foods versus prompted to think about the immediate pleasurable qualities of consuming those same unhealthy, yet palatable foods. We will then determine whether individual differences in these neural responses predict future health behaviour change. We will focus on regions within the prefrontal cortex and striatum. Second, we will probe structural-functional connectivity associations, which will help us better understand how individual differences in brain function arise from differences in underlying brain structure.

Administration of Outcomes Measures: At baseline, participants will attend the cognitive assessment session at Vancouver General Hospital. If a participant is interested and eligible for the MRI scanning, then the cognitive assessment session will take place at the UBC 3T Magnetic Resonance Imaging Centre. For the cognitive assessment, participants will complete the

computer-based tasks, MoCA (baseline only) and the CHAMPS questionnaire. Participants will wear the SenseWear for 7 days and complete the online questionnaire, consisting of KOOS and Partners in Health. At the end of Month 2, 4 and 6, participants will wear the SenseWear for 7 days, complete the online questionnaire, and attend the cognitive assessment session again at Vancouver General Hospital.

Power Calculation and Data Analysis: From MPAP and other community resources mentioned above, we will be able to recruit 60 participants in 10 months. For a proof-of-concept study, it is reasonable to expect moderately large difference between groups after the intervention. Our pilot study with arthritis patients found an average of 71.8 minutes (SD=96.2) of activities at 3 METs bouted at 10-minute intervals. Assuming an attrition rate of approximately 15%, we anticipate 50 of the 60 participants will complete the study. With a sample size of 50 and  $\alpha$ -level of 0.05, we will have 96.3% power to detect a between-group difference of at least 10 minutes after the intervention.

An intention-to-treat analysis will be performed for the RCT. The main analysis will include the bouted mean MVPA minutes, bouted mean sedentary minutes, the KOOS, the Partners in Health Scale, and the cognitive assessments. For the main comparison, we will use analysis of covariance (ANCOVA) to compare between the Intervention Group and Control Group at 2 months, using the baseline measure as a covariate. In addition, ANCOVA will be used to assess the difference between the Intervention Group at 2 months and the Control Group at 4 months, with the baseline measure as a covariate. We anticipate that the two groups should be similar if the delay of 2 months in the Control Group does not influence the effect of the intervention. We will also use repeated measure ANOVA to assess the within group differences over the four assessment periods.

For the qualitative interviews, we will conduct an iterative content analysis, whereby codes will be identified and revised as interviews are analyzed. Initial open coding will be followed by clustering the labels into thematic categories. Quotes representative of the thematic categories will be identified to illustrate participants' perspectives on physical activity, nature of activities, and their experiences with the intervention. These data will inform the interpretation of statistical analyses and to refine the model of care, for example, ways for therapists to provide feedback about physical activity to patients or propose activities to facilitate health behaviour change.

## **5.0 LIMITATIONS**

A limitation is that the intervention requires participants to use the device continuously for two months. To minimize non-compliance, we choose Fitbit Flex, which can be worn on the wrist 24 hours a day including during water-based activities. Our pilot study suggests that it is feasible for people with joint pain to use the device continuously for an extended period. Also, through the weekly phone call, the PT will ensure the device is used properly. It is possible that participants may gain access to a Fitbit during the non-intervention period since it is commercially available. To encourage adherence to the protocol, participants will be informed that the Fitbit will be returned to them for their continued use, free of charge, at the end of the study.

## **6.0 SIGNIFICANCE**

For patients with OA, a successful strategy to improve physical activity has far reaching implications, such as better mobility and quality of life. In the short term, this project will benefit MPAP patients with knee OA, and those in the community with knee pain or knee OA, by developing a new model to initiate a physically active lifestyle while they are on the

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physiotherapy wait list. Although OA is our current focus, the proposed model can be expanded to serve patients with other chronic diseases in the future.

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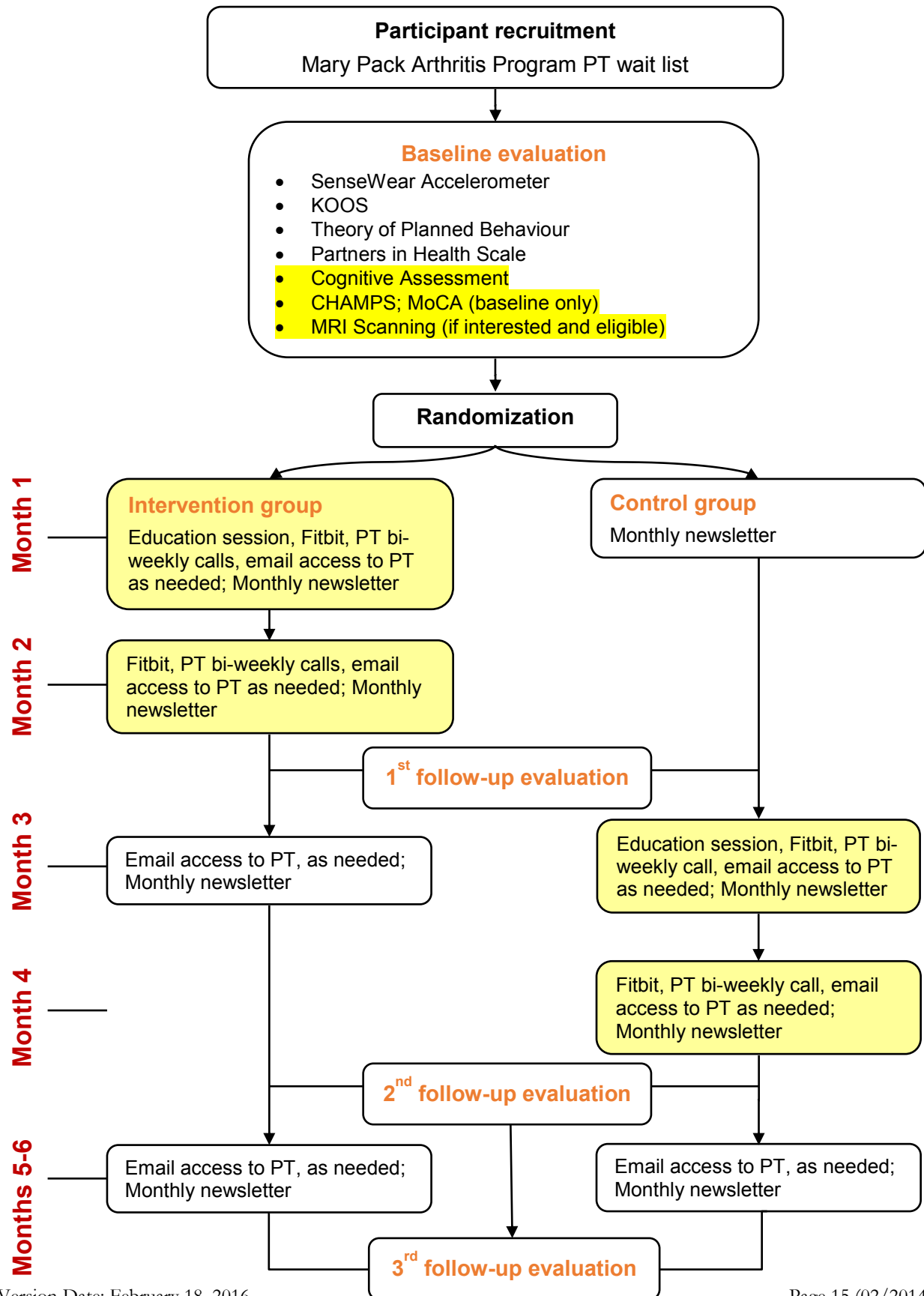
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**Table 1: Proof-of-concept study timeline**

Task	Month							
	3	6	9	12	15	18	21	24
Obtain ethics approval (Month 1)								
Participant recruitment (Month 2-11)								
Data collection (Month 2-17)								
Telephone interviews (Month 4-18)								
RCT data analysis (Month 18-20)								
Interview & data analysis (Month 6-22)								
End-of-project KT (Month 21-24)								

**Figure 1: Fitbit™ Flex**

Fitbit Flex is a wireless physical activity monitoring device which is designed to wear as a wrist band. It is a compact gross body movement tracking device that tracks and displays steps walked, stairs climbed and gross physical exertion. It is water resistant and can be worn during water-based activities. It can also be linked to several social network websites including Facebook and My Fitness Pal. This allows users to share experiences and successes with their online friends.

**Figure 2: Study procedure**

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